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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,305	03/02/2004	Steve Koh	A04P1019	4653

36802 7590 08/26/2005

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
ROSENZWEIG, JASON	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,305	KOH, STEVE	
	Examiner	Art Unit	
	Jason E. Rosenzweig	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/2/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Section labeled "Cross-Reference to Related Applications" mentions a copending application titled "System and Method for Diagnosing and Tracking Congestive Head Failure Based on the Periodicity of Cheyne-stokes Respiration Using an Implantable Medical Device" but does not list the Application Serial No.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, and 8-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho (US 6641542) et al.

Regarding claim 1, The Cho patent discloses: A method for distinguishing Cheyne-stokes Respiration (CSR) within a patient caused by central sleep apnea (CSA) from CSR caused by congestive heart failure (CHF) using an implanted medical device, the method comprising:
detecting a periodicity associated with CSR for the patient' (Pg. 9, Ln. 45), and
determining whether the CSR of the patient is caused by CSA or
by CHF based on the periodicity (Pg. 9, Ln. 46).

Regarding claim 2, The Cho patent discloses: The method of claim 1 wherein detecting the periodicity is performed to detect a time period representative of periodic breathing during CSR (Pg. 9, Ln. 45).

Regarding claim 3, The Cho patent discloses: The method of claim 2 wherein detecting a time period associated with CSR for the patient comprises:

detecting sleep (Figure 6, Element 610); detecting an episode of CSR during sleep (Figure 6, Element 630); and determining the average duration of periods of sleep apnea during CSR (Figure 6, Element 660), determining the average duration of periods of breathing between the periods of sleep apnea during CSR, combining the average duration of periods of sleep apnea with the average duration of periods of breathing (See Abstract).

Regarding claim 4, The Cho patent discloses: The method of claim 3 wherein determining the average duration of periods of sleep apnea during CSR and determining the average duration of periods of breathing between the periods of sleep apnea during CSR are performed using on one or more of thoracic impedance (Figure 5, Element 510-2), AV delay; R-R oscillations (Pg. 5, Ln. 12).

Regarding claim 5, The Cho patent discloses: The method of claim 1 wherein determining whether the CSR of the patient is caused by CSA or by CHF based on the periodicity comprises:
comparing a time period associated with CSR against a predetermined discrimination threshold; and if the time period exceeds the discrimination threshold, generating a signal indicating that the CSR is induced by CHF, otherwise generating a signal indicating that the CSR is induced by CSA (Pg 9, Ln. 45).

Regarding claim 6, The Cho patent discloses: The method of claim 5 and further comprising calculating the discrimination threshold by: sensing signals representative of thoracic impedance (Pg. 7, Ln. 19); low pass filtering the impedance signals; calculating a derivative of the filtered impedance signal; identify zero-crossing points within the derivative of the filtered impedance signal; integrating the derivative of the filtered impedance signal between each pair of consecutive zero-crossing points to generate a set of integral values; and calculating moving average of integrated values for use as the threshold. Official notice is taken on the use of low pass filtering since it is just a method of reducing noise in the signal, which is commonly required with implantable medical devices since the signals are of very low voltages. Official notice is also taken on the use of calculating a moving average since this is a common way of smoothing data when using threshold type decision-making.

Regarding claim 8, The Cho patent discloses: The method of claim 3 further comprising detecting arousal of the patient from sleep and rejecting any determination of the periodicity associated with CSR if arousal from sleep occurred during the episode of CSR (Fig. 6, Element 610).

Regarding claim 9, The Cho patent discloses: The method of claim 8 wherein detecting arousal of the patient from sleep is performed based on accelerometer signals (Figure 5, Element 520).

Regarding claim 10, The Cho patent discloses: The method of claim 1 further comprising recording diagnostic data relevant to the determining of whether the CSR of the patient is caused by CSA or by CHF (Pg. 9, Line 45).

Regarding claim 11, The Cho patent discloses: The method of claim 1 further comprising determining whether the patient is asleep (Figure 6, Element 610).

Regarding claim 12, The Cho patent discloses: The method of claim 11 wherein determining whether the patient is asleep is performed by based on patient activity levels (Figure 6, Element 610) or blood carbon dioxide levels.

Regarding claim 13, The Cho patent discloses: The method of claim 1 further comprising delivering therapy to the patient (Figure 6, Element 690).

Regarding claim 14, The Cho patent discloses: The method of claim 1 further comprising delivering electrical nerve stimulation to at least one phrenic nerve of the patient (Pg. 10, Ln. 45). The hypoglossal nerve branches off to the phrenic nerve.

Regarding claim 15, The Cho patent discloses: The method of claim 1 further comprising delivering cardiac resynchronization therapy to the heart of the patient (Pg. 4, Ln. 55).

Regarding claim 16, The Cho patent discloses: The method of claim 1 further comprising evaluating the severity of CHF if the CSR of the patient is caused by CHF (Pg. 9, Paragraph starting at Ln. 54).

Regarding claim 17, The Cho patent discloses: The method of claim 1 further comprising delivering therapy to the patient based on the severity CHF (Pg. 9, Ln. 60).

Regarding claim 18, The Cho patent discloses: A system for distinguishing Cheyne-slokes Respiration (CSR) within a patient caused by central sleep apnea (CSA) from CSR caused by congestive heart failure (CHF) using an implanted medical device, comprising: a CSR periodicity determination unit operative to determine a periodicity associated with CSR (Pg. 9, Ln. 45) for the patient; and a CSR discrimination unit operative to determine whether the CSR of the patient is caused by CSA or by CHF based on the periodicity associated with CSR for the patient (Pg. 9, Ln 46).

Regarding claim 19, The Cho patent discloses: The implantable cardiac stimulation system of claim 18 and further comprising: a CSA/CHF therapy controller operative to control delivery of therapy to the patient based on the determination of whether the CSR of the patient is caused by CSA or by CHF (Pg. 9, Paragraph starting at Ln. 54).

Regarding claim 20, The Cho patent discloses: A system for distinguishing Cheyne-stokes Respiration (CSR) within a patient caused by central sleep apnea (CSA) from CSR caused by congestive heart failure (CHF) using an implanted medical device, comprising:

means for detecting the onset of CSR (Pg. 9, Ln. 45); means for detecting a periodicity associated with CSR for the patient(Pg. 9, Ln. 45); and means for determining whether the CSR of the patient is caused by CSA or by CHF based on the periodicity (Pg. 9, Ln. 46).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho (US 6641542).

5. Regarding Claim 7, official notice has been taken that "In all types of sleep apnea, breathing may become abnormally slow and shallow, or breathing may suddenly stop for at least 10 seconds (sometimes up to 1 minute), then resume.", According to multiple sources, including the Merck Manual, these are standard symptoms of any type of sleep apnea. It would therefore be obvious to set a time threshold of CSR to a value greater than 10 seconds upon the review of publicly available medical literature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Rosenzweig
Patent Examiner
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Robert Pezzuto
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